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Sir:

Transmitted herewith for filing under 37 CFR 1.53(b) is a(n): (X) Utility ( ) Design
( ) original patent application,
( ) continuation-in-part application

INVENTOR(S): **Gust H Bardy**

TITLE: **External Atrial Defibrillator And Method For Personal Termination Of Atrial Fibrillation**

Enclosed are:

(X) The Declaration and Power of Attorney. (X) signed ( ) unsigned or partially signed

(X) 5 sheets of drawings (one set) ( ) Associate Power of Attorney

( ) Form PTO-1449 ( ) Information Disclosure Statement and Form PTO-1449

( ) Priority document(s) ( )(Other) _____ (fee $_____)

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Charge $ 778 to Deposit Account 50-1078. At any time during the pendency of this application, please charge any fees required or credit any over payment to Deposit Account 50-1078 pursuant to 37 CFR 1.25. Additionally please charge any fees to Deposit Account 50-1078 under 37 CFR 1.16, 1.17,1.19, 1.20 and 1.21. A duplicate copy of this sheet is enclosed.

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By _____

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Respectfully submitted,

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By _____

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APPLICATION FOR UNITED STATES LETTERS PATENT

of

Gust H. Bardy
and
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for

EXTERNAL ATRIAL DEFIBRILLATOR AND METHOD FOR PERSONAL TERMINATION OF ATRIAL FIBRILLATION

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EXTERNAL ATRIAL DEFIBRILLATOR AND METHOD FOR PERSONAL TERMINATION OF ATRIAL FIBRILLATION

TECHNICAL FIELD

The invention relates generally to medical devices, and more particularly to an external atrial defibrillator and method for terminating atrial fibrillation.

BACKGROUND OF THE INVENTION

Atrial fibrillation (AF), which lay persons know as heart palpitations, is a commonly occurring cardiac arrhythmia. Generally, an AF episode is not life threatening, and the patient is functional during the episode. Some patients, however, feel under the weather, feel dizzy, or even lose consciousness during an AF episode. Nevertheless, even in the most severe cases, AF episodes without secondary sequelae and lasting less than 48 hours are thought to have no long-term adverse effects on a patient's health. Conversely, among other consequences, episodes lasting 48 hours or longer increase a patient's risk of stroke. Therefore, a patient's physician usually instructs him/her to seek medical treatment if an AF episode does not spontaneously terminate within 24 hours. This gives the patient sufficient time to actually receive treatment within the 48-hour safety window.

Referring to **FIGS. 1** and **2**, AF is characterized by irregularly distributed R-R intervals in a patient's electrocardiogram. **FIG. 1** is portion of a patient's electrocardiogram that includes one R-R interval. The electrocardiogram includes P, Q, R, S, and T waves, and the R-R interval is defined as the interval between the upper peaks of adjacent R waves. **FIG. 2** is a plot of the respective lengths of a patient's R-R intervals during an AF episode. In the electrocardiogram of a patient having a normal heart rhythm, the lengths of adjacent R-R intervals differ from one another by no more than a few milliseconds (ms), and thus are approximately equal. Therefore, during a period of normal heart rhythm, the plotted lengths of the R-R intervals would lie on or near the dashed line ***10*** in a normal distribution pattern. But during an AF episode, the plotted lengths of the R-R intervals differ significantly and randomly from one another. Therefore,

during an AF episode, the plotted lengths ***12*** of the R-R intervals lie in a random distribution pattern with the appearance of a "bee swarm".

There are several preventative and termination treatments available to patients with AF. Preventative treatments such as anti-arrhythmic drug therapy help prevent AF episodes from occurring, and termination treatments such as cardioversion terminate AF episodes once they have begun. As discussed below, some of these treatments are often expensive and/or inconvenient.

An external atrial defibrillator is a device that a cardiologist uses to apply one or more cardioverting electrical pulses, *i.e.*, shocks, to the patient in order to terminate an AF episode. As discussed above, the cardiologist instructs his patient to notify the cardiologist's office if an AF episode lasts more than 24 hours. The cardiologist then admits the patient to the hospital on an in-patient or out-patient basis. While in the hospital, the patient is anesthetized and is shocked one or more times until the AF episode terminates. Unfortunately, this procedure costs approximately $1000 – $5000 per session depending upon the procedure location within the hospital, and thus is relatively expensive. In addition, this procedure is burdensome to the patient for a number of reasons. For example, he/she often misses at least a day of work to undergo cardioversion. Furthermore, because the lingering effects of the anesthesia render him/her temporarily unfit to drive, the patient must find someone to drive him/her home from the hospital after the procedure. Because many AF patients require this procedure several times per year, the cumulative costs and burdens associated with this procedure can be quite substantial.

An internal atrial defibrillator is a device that is implanted within a patient's body and that applies one or more cardioverting electrical shocks directly to the patient's heart in order to terminate an AF episode. A manual model, such as the InControl Metrix, allows the patient to shock himself when he wishes to terminate an AF episode. In one known device, the patient initiates a shock by using a magnet to toggle a subcutaneous switch. Unfortunately, the implant surgery may cause discomfort to the patient, and complications such as infection may arise following surgery. Furthermore, additional surgeries can be required to replace the batteries or to repair or replace a defective unit. Alternatively, the internal defibrillator may include circuitry that detects an AF episode and automatically

shocks the patient to terminate it. Unfortunately, in addition to the problems described above for the manual model, the automatic model may embarrass the patient. For example, a defibrillator shock affects not only the heart muscle, but often contracts most, if not all, of the voluntary muscles in the patient's thorax. Unfortunately, these contractions often cause the patient to "jump" uncontrollably. Therefore because the patient has no control over when the defibrillator delivers the shock, the shock, and thus this potentially embarrassing side effect, may occur during work or a social occasion.

Therefore, what is needed is an external atrial defibrillator that a patient or caretaker can use safely in the patient's own home.

SUMMARY OF THE INVENTION

In one aspect of the invention, an atrial defibrillator includes a pair of defibrillator pads, a shock generator, and an analyzer. The pads are applied to the outside of a patient's body, and the shock generator delivers a shock to the patient via the pads. The analyzer receives a cardiac signal from the patient, determines from the signal whether the patient is experiencing atrial fibrillation, and enables the shock generator if the patient is experiencing atrial fibrillation.

Unlike conventional external atrial defibrillators, such an atrial defibrillator can be used by a layperson in the comfort of a patient's own home. Furthermore, such a defibrillator does not cause the surgery-related problems associated with implantable atrial defibrillators. Moreover, because the patient can choose when to receive a shock, such a defibrillator is less likely to embarrass the patient than automatic implantable defibrillators are.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is portion of a patient's electrocardiogram that includes an R-R interval.

FIG. 2 is a plot of an R-R-interval distribution for a patient experiencing an AF episode.

FIG. 3 is a diagram of an atrial defibrillator according to an embodiment of the invention, and a patient connected to the defibrillator.

FIG. 4 is a schematic block diagram of the atrial defibrillator of **FIG. 3** according to an embodiment of the invention.

FIG. 5 is a plot of an R-R-interval distribution for a patient experiencing premature ventricular contractions (PVC).

FIG. 6 is a portion of an electrocardiogram for a patient experiencing Ashman's phenomenon.

FIG. 7 is a flow diagram of an atrial-defibrillation procedure that incorporates the atrial defibrillator of **FIG. 3** according to an embodiment of the invention.

DESCRIPTION OF THE INVENTION

FIG. 3 is a block diagram of an atrial defibrillator ***20*** according to an embodiment of the invention, and a patient ***22*** connected thereto. The defibrillator ***20*** includes a portable shock/analyze unit ***24*** for generating an atrial-defibrillation (ADF) shock, and includes electrode pads ***26*** and ***28*** for delivering the ADF shock to the patient ***22***. (The pad ***26*** is in dashed line to indicate that it is coupled to the patent's back.) The unit ***24*** includes a control panel ***30***, which allows an operator (not shown) to input commands such as a shock command to the unit ***24***, and includes an identification verifier ***32***, which prevents the unit ***24*** from generating a shock if the operator is unauthorized to operate the unit. The pads ***26*** and ***28*** are coupled to the unit ***24*** via wires ***34*** and ***36***, respectively, are attached to the patient ***22*** with a conventional adhesive, and include a conventional contact gel that enhances the electrical conductivity between the pads and the patient's skin. Although an anterior-posterior placement of the pads ***26*** and ***28*** is shown and is believed to be the most effective placement for terminating an AF episode, one can use the shock unit ***24*** with other pad placements as well.

In operation, the shock/analyze unit ***24*** analyzes the patient's heart rhythm, determines whether the patient ***22*** is experiencing an AF episode, and generates an ADF shock in response to the operator's command if the patient ***22*** is experiencing an AF episode and other conditions are met. The unit ***24*** receives a cardiac signal such as an electrocardiogram from the patient ***22*** via the pads ***26*** and ***28*** or by other conventional means. The unit ***24*** analyzes the cardiac signal

to determine whether the patient is experiencing an AF episode. If the patient is experiencing an AF episode, then the identification verifier ***32*** determines whether the operator is authorized to shock the patient ***22***. If the operator is authorized, the unit ***24*** generates an ADF shock in response to the operator entering a shock command via the panel ***30***. As discussed below in conjunction with **FIGS. 4** and **5**, the verifier ***32*** checks the operator's authorization primarily for safety reasons. For example, in one embodiment the verifier ***32*** prevents the patient ***22*** from shocking himself/herself. After generating the ADF shock, the unit ***24*** analyzes the cardiac signal again to determine whether the AF episode has terminated, informs the operator and patient of the analysis results, and suggests further treatment options if the AF episode has not terminated. Conversely, if the patient ***22*** is not experiencing an AF episode or if the operator is unauthorized to operate the defibrillator ***20***, then the unit ***24*** does not generate an ADF shock regardless of the commands that the operator enters via the panel ***30***.

The atrial defibrillator ***20*** provides many advantages over prior atrial defibrillators. Unlike conventional external defibrillators, the portability and analysis capability of the shock/analyze unit ***24*** make the defibrillator ***20*** ideal for use by laypersons outside of the hospital and doctor's office. Therefore, the defibrillator ***20*** significantly reduces the costs and inconveniences associated with conventional external cardioversion techniques, and may even be a convenient alternative to anti-arrhythmic drug therapy for some patients. Furthermore, unlike implantable atrial defibrillators, the defibrillator ***20*** has no surgery-related risks and allows the patient ***22*** to receive an ADF shock at a time and place of his/her own choosing.

Although one embodiment of the defibrillator ***20*** is discussed for example purposes, the inventors contemplate other embodiments. For example, the unit ***24*** may lack the non-patient operator verifier ***32*** so that the patient ***22*** can shock himself/herself should the diagnostic algorithm allow.

FIG. 4 is a schematic block diagram of the shock/analyze unit ***24*** of **FIG. 3** according to an embodiment of the invention. In addition to the control panel ***30*** and the identification verifier ***32***, the unit ***24*** includes a shock-generator circuit ***40***, an analyze/synchronize circuit ***42***, a memory ***44***, and a communicator ***46***.

In operation, the circuit ***42*** first analyzes the cardiac signal from the patient ***22*** via the pads ***26*** and ***28*** (**FIG. 3**) to determine if the patient is experiencing an AF episode. If the patient ***22*** is not experiencing an AF episode, then the circuit ***42*** informs the patient and operator via the communicator ***46*** — which may be a visual display or a speech synthesizer — and the unit ***24*** delivers no ADF shocks. If the patient is experiencing an AF episode, the circuit ***42*** informs the patient and operator via the communicator ***46***, enables the circuit ***40***, and synchronizes the circuit ***40*** such that it generates the ADF shock during a desired portion of the cardiac signal. Thus, even if the operator enters a shock command via the control panel ***30***, the circuit ***42*** delays the circuit ***40*** from generating the ADF shock until the occurrence of the desired portion of the cardiac signal. After the ADF shock, the circuit ***42*** analyzes the cardiac signal to determine if the AF episode has terminated. If it has, the circuit ***42*** informs the patient and operator via the communicator ***46*** and disables the circuit ***40*** from generating more ADF pulses. If the AF episode has not terminated, the circuit ***42*** informs the patient and operator and allows the circuit ***40*** to generate another ADF shock if the patient so desires. But as discussed below, the circuit ***42*** may disable the circuit ***40*** after the patient has received a predetermined maximum number of ADF shocks.

Still referring to **FIG. 4**, the design and operation of the shock-generator circuit ***40*** and the analyze/synchronize circuit ***42*** are discussed in more detail.

In one embodiment, the shock-generator circuit ***40*** is conventional and includes a power supply ***48***, shock source ***50***, sensor ***52***, timer ***54***, controller ***56***, counter ***58***, and pad coupler ***60***. The supply ***48*** charges the shock source ***50***, and in the absence of another power supply, provides power to the other circuitry of the shock/analyze unit ***24***. When the pad coupler ***60*** couples the source ***50*** to the wires ***34*** and ***36***, the shock source ***50***, which is a capacitor bank in one embodiment, discharges to generate an ADF shock pulse. The sensor ***52*** provides a sensor signal to the timer ***54*** when the pulse decays to a predetermined level. The timer ***54*** provides a pulse timing signal to the controller ***54***. The controller ***56*** activates the pad coupler ***60*** to generate an ADF pulse, deactivates the pad coupler ***58*** to terminate an ADF pulse, and may reverse the polarity of the coupler ***58*** to reverse the polarity of a biphasic or

multiphasic ADF pulse. The counter ***58*** increments or decrements by one each time the controller ***56*** activates the pad coupler ***58*** to generate a new ADF pulse.

In operation, when it receives respective enable signals from the identification verifier ***32***, the analyzer ***44***, and the counter ***58***, the shock controller ***56*** activates the pad coupler ***60*** in response to a shock command from the control panel ***30***. The active coupler ***60*** couples the shock source ***50*** to the pads ***26*** and ***28***, and thus the energy stored in the source ***50*** discharges into the patient ***22*** (**FIG. 3**). This transfer of energy constitutes the ADF pulse. The sensor ***52*** monitors the ADF pulse, and, when it decays to a predetermined level, the sensor ***52*** signals the timer ***54***. The timer ***54*** waits a predetermined time after receiving the sensor signal, and then provides a timing signal to the controller ***56***. If the controller ***56*** is programmed to generate a uniphasic ADF pulse, then the controller ***56*** deactivates the pulse coupler ***60***, which uncouples the shock source ***50*** from the pads ***26*** and ***28*** to terminate the pulse. If, on the other hand, the controller ***56*** is programmed to generate a biphasic ADF pulse, then the controller ***56*** causes the pulse coupler ***60*** to reverse the polarity of the connection between the shock source ***50*** and the pads ***26*** and ***28***. The sensor ***52*** then monitors this reversed-polarity portion of the pulse, and, when this portion of the pulse decays to a predetermined level, the sensor ***52*** again signals the timer ***54***. The timer ***54*** waits a predetermined time after receiving the sensor signal and then provides another timing signal to the controller ***56***, which deactivates the pulse coupler ***60*** to terminate the biphasic ADF pulse. Although the shock controller ***56*** is described as generating uniphasic or biphasic ADF pulses, the shock controller ***56*** can also generate multiphasic ADF pulses in a similar manner.

As is known, the ADF pulses generated by the shock-generator circuit ***40*** can have a wide range of voltage and energy levels. For example, the energy levels of ADF pulses are typically within a range of approximately 70–400 Joules (J). Because AF episodes are difficult to terminate with one ADF pulse, particularly with a lower-energy pulse, in one embodiment the circuit ***40*** generates each ADF pulse having an energy of at least 200 J. This reduces the chance that the patient will require multiple ADF pulses to terminate an AF episode. Typically, multiple pulses are more uncomfortable to a patient than a single pulse, even if the single pulse has a higher energy level than each of the multiple pulses.

Therefore, terminating an AF episode in only one pulse significantly reduces the patient's discomfort.

Shock-generator circuits such as the shock-generator circuit ***40*** are discussed in many references including U.S. Patent No. 5,735,879 to Gliner et al. for "Electrotherapy Method for External Defibrillators", which is incorporated by reference.

Still referring to **FIG. 4**, as discussed above, the analyze/synchronize circuit ***42*** analyzes a cardiac signal to determine if the patient ***22*** is experiencing an AF episode, and if so, enables the shock-generator circuit ***40*** and synchronizes the generation of the ADF pulse to the cardiac signal. If, on the other hand, the patient is not experiencing an AF episode or has received the maximum number of ADF pulses allowed, the circuit ***42*** may disable the circuit ***40*** from generating another ADF shock.

In one embodiment, the analyze/synchronize circuit ***42*** determines whether the patient is experiencing an AF episode by analyzing the differences between the R-R intervals in the patient's electrocardiogram (**FIG. 1**). Specifically, the circuit ***42*** samples a plurality of consecutive R-R intervals, computes the respective differences between the length of each sampled R-R interval and the lengths of the adjacent R-R intervals, and determines that the patient is experiencing an AF episode if at least a predetermined number of these differences equals or exceeds a predetermined difference threshold. For example, suppose the number of samples is ***20***, the difference threshold is 40 ms, and the predetermined number is 5. Therefore, the circuit ***42*** detects an AF episode if 5 or more of the R-R-interval differences equal or exceed 40 ms. Alternatively, the circuit ***42*** may repeat this procedure for multiple groups of sampled R-R intervals and detect AF if the predetermined number of differences within each group equals or exceeds the predetermined difference threshold. For example, suppose there are 10 groups of 20 samples each. Therefore, the circuit ***42*** detects an AF episode if 5 or more of the R-R-interval differences within each group equal or exceed 40 ms. Circuits and techniques for performing such an R-R interval analysis are well known, and, therefore, are omitted for clarity.

In another embodiment, to increase diagnostic specificity, the analyze/synchronize circuit ***42*** determines whether the patient is experiencing an

AF episode by analyzing the R-R intervals as discussed above and by analyzing the QRS signals of the patient's electrocardiogram. Referring to **FIG. 1**, a QRS signal is a combination of the Q, R, and S waves. During an AF episode, the patient's QRS signals typically have a normal shape. Therefore, the circuit ***42*** samples several of the QRS signals from the patient's electrocardiogram and compares each of their shapes to a normal QRS shape that is stored in the memory ***44***. (The normal QRS shape is the shape of a QRS signal that was previously sampled and stored while the patient was experiencing a normal heart rhythm.) If the respective differences between the shapes of the sampled QRS signals and the shape of the normal sinus rhythm QRS signal are all less than a predetermined QRS difference, then the circuit ***42*** determines that the sampled QRS signals are normal. Therefore, if the sampled QRS signals are normal and the R-R-interval analysis indicates an AF episode as discussed above, then the circuit ***42*** determines that the patient is experiencing an AF episode. If, however, the shapes of at least a predetermined number of the sampled QRS signals differ from the shape of the normal QRS signal by at least the predetermined QRS difference, then the circuit ***42*** determines that the sampled QRS signals are abnormal. Therefore, if the sampled QRS signals are abnormal, then the circuit ***42*** determines that the patient is not experiencing an AF episode regardless of the results of the R-R-interval analysis. Furthermore, because abnormal QRS signals may indicate a serious arrhythmia such as ventricular fibrillation (VF), the circuit ***42*** informs the operator and patient to seek prompt medical attention for the patient. Alternatively, the shock/analyze unit ***24***, upon identification of VF, may revert to a standard AED for VF. Circuits and techniques for comparing the shapes of QRS signals are well known, and, therefore, are omitted for clarity.

In yet another embodiment, the analyze/synchronize circuit ***42*** determines whether the patient is experiencing an AF episode by first determining the patient's heart rate and then performing either of the AF detection techniques discussed above. Typically, the heart rate of a patient experiencing an AF episode is in a range of approximately 40–200 beats per minute. Therefore, if the circuit ***42*** determines that the patient's heart rate is within this range, it proceeds with one of the AF-detection techniques as discussed above. Conversely, if the circuit ***42*** determines that the patient's heart rate is outside of this range, it informs

the patient and operator that the patient is not experiencing an AF episode, and thus disables the shock-generator circuit ***40*** for atrial cardioversion. Circuits and techniques for determining a patient's heart rate are well known, and, therefore, are omitted for clarity.

Referring to **FIGS. 4, 5**, and **6**, in still another embodiment, the analyze/synchronize circuit ***42*** distinguishes between AF and other arrhythmias that the above-described AF-detection techniques may erroneously interpret as an AF episode. **FIG. 5** is a plot of an R-R-interval distribution for a patient experiencing premature ventricular contractions (PVC). Like AF, the lengths of adjacent R-R intervals of a patient experiencing PVC can differ significantly. But unlike AF, the R-R-interval distribution for PVC lies primarily within three distribution regions ***70***, ***72***, and ***74***. Therefore, if the circuit ***42*** detects such a distribution pattern, it determines that the patient is not experiencing an AF episode even if the above-described R-R-interval analysis or combined R-R-interval/QRS analysis indicates otherwise. **FIG. 6** is an electrocardiogram of a patient experiencing Ashman's phenomenon, which is characterized by a wider-than-normal QRS signal ***76*** that follows an Ashman sequence. An Ashman sequence includes a shorter-than-normal R-R interval ***78***, a normal QRS signal ***80***, and a longer-than-normal R-R interval ***82*** (only a portion of which is shown in **FIG. 6**). Because Ashman's phenomenon affects the QRS signals but not the R-R intervals, it is only a concern when the circuit ***42*** uses the combined R-R-interval/QRS analysis described above. Therefore, if the R-R-interval portion of the analysis indicates an AF episode but the QRS portion of the analysis indicates no AF episode, the circuit ***42*** determines whether the abnormal QRS signals follow respective Ashman sequences. If this is the case, then the circuit ***42*** determines that the patient is experiencing an AF episode regardless of the results of the QRS portion of the analysis. Circuits and techniques for detecting Ashman's sequences are well-known, and, therefore, are omitted for clarity.

Still referring to **FIG. 4**, in one embodiment, the analyze/synchronize circuit ***42*** synchronizes the generation of the ADF pulse to the rising edge of an R wave. Such synchronization reduces the chance that the ADF pulse will induce

other more serious arrhythmia such as VF. Circuits and techniques for performing such synchronization are well-known, and, therefore, are omitted for clarity.

In another embodiment, the analyze/synchronize circuit ***42*** synchronizes the generation of the ADF pulse to the rising edge of an R wave that follows a normal or long R-R interval. This is because synchronizing an ADF pulse to an R wave that follows a short R-R interval increases the chances that the pulse will cause the patient to experience a more serious arrhythmia such as VF. A circuit and technique for performing such synchronization are discussed in U.S. Patent No. 5,207,219 to Adams et al., which is incorporated by reference.

Still referring to **FIG. 4**, after the shock-generator circuit ***40*** generates the ADF pulse, the analyze/synchronize circuit ***42*** uses techniques similar to the AF-detection techniques discussed above to determine whether the AF episode has terminated. In one embodiment, the circuit ***42*** analyzes the differences between the R-R intervals in the patient's post-shock electrocardiogram and determines that the AF episode has terminated if at least a predetermined number of these differences is less than a predetermined difference threshold. For example, suppose that the number of samples is ***20***, and the difference threshold is 40 ms, and the predetermined number is 15. Therefore, the circuit ***42*** detects termination of the AF episode if at least 15 of the R-R-interval differences are less than 40 ms. In another embodiment, the circuit ***42*** also compares the post-shock QRS signals with the stored normal QRS signal. The circuit ***42*** detects that the AF episode has terminated if the post-shock QRS signals match the normal QRS signal and the results of the R-R-interval analysis indicate termination of the AF episode.

Although the shock/analyze unit ***24*** is described in conjunction with **FIG. 4** as including a number of functional circuit blocks, the unit ***24*** may instead include one or more processors that are programmed to perform the functions of these circuit blocks.

FIG. 7 is a flow diagram of an atrial defibrillation procedure that incorporates the atrial defibrillator ***20*** of **FIG. 3** according to an embodiment of the invention.

Referring to block ***90***, the operator activates the defibrillator ***20*** and attaches the pads ***26*** and ***28*** to the patient's body (**FIG. 3**).

Referring to blocks ***92*** and ***94***, the defibrillator ***20*** analyzes the patient's cardiac signal and determines whether the patient is experiencing an AF episode as discussed above in conjunction with **FIGS. 4**, **5**, and **6**. Referring to blocks ***96*** and ***98***, if the patient is not experiencing an AF episode, then the defibrillator ***20*** informs the patient and operator and instructs the operator to remove the pads ***26*** and ***28*** from the patient.

Referring to blocks ***100*** and ***102***, if the patient is experiencing an AF episode, then the defibrillator ***20*** "asks" the patient if he/she has waited for at least a specified waiting period since the onset of the AF episode. Such a waiting period allows the AF episode a chance to spontaneously terminate without the need for an ADF shock. In one embodiment, the waiting period is approximately 6 hours. The patient or the operator enters a "yes" or "no" response. If a "no" is entered, then the defibrillator ***20*** instructs the operator to remove the pads ***26*** and ***28*** (block ***98***) and to wait the remainder of the waiting period before using the defibrillator ***20***.

Referring to block ***104***, if the patient has waited for at least the specified waiting period, then the defibrillator asks him/her if there is another authorized person, *i.e.*, the operator, available to administer the ADF shock. If the patient answers " no", then, referring to blocks ***106*** and ***98***, the defibrillator ***20*** informs the patient that he cannot shock himself and instructs the patient to remove the pads ***26*** and ***28***. As discussed above, the patient is not allowed to shock himself for safety reasons. For example, there is a very small risk that an ADF pulse, even if properly synchronized to the cardiac signal, may cause the patient to experience VF. A patient is typically unconscious during a VF episode, which can lead to the patient's death. Therefore, if the ADF shock induces VF and no other person is present, then the patient, who will be unable to call for help, will die. The presence of an operator, however, allows the rare induction of VF to be promptly treated with the defibrillator ***20*** or a portable VF defibrillator (not shown) and allows the operator to call an ambulance and even administer cardiopulmonary resuscitation (CPR). For additional safety, the identification verifier ***32*** (**FIGS. 3** and **4**) insures that only an authorized operator can initiate the ADF shock. For example, the verifier ***32*** may require the operator to enter a secret code or may scan a physical characteristic such as a fingerprint or retina

and compare it to an image of the characteristic stored in the memory ***44***. Or, the defibrillator ***20*** may include circuitry that determines whether the operator is attached to the pads ***26*** and ***28***. If the operator is so attached, then the defibrillator ***20*** determines that the operator is actually the patient and is attempting to shock himself, and thus disables the shock-generator circuit ***40***.

Referring to block ***108***, if an authorized operator is present, then the defibrillator ***20*** informs him that he/she can initiate an ADF shock when the patient is ready. For example, the patient may want to delay the initiation of the shock for several hours so that he/she can take a sedative such as Valium and allow the sedative sufficient time to take effect. Once the patient is ready and the diagnostic algorithm is satisfied, the operator initiates the ADF shock by entering a shock command via the control panel ***32*** (**FIGS. 3** and **4**).

Referring to block ***110***, the defibrillator ***20*** waits for the operator to enter the shock command. Referring to blocks ***112*** and ***114***, once the operator enters the shock command, the defibrillator ***20*** generates and delivers the shock to the patient and updates the shock counter ***58*** (**FIG. 4**), which the defibrillator previously reset to an initial count value such as zero.

Referring to blocks ***116*** and ***118***, the defibrillator ***20*** analyzes the post-shock cardiac signal from the patient and determines whether the AF episode has terminated. In one embodiment, the defibrillator ***20*** uses one or more of the AF-termination-detection procedures discussed above in conjunction with **FIGS. 4, 5,** and **6**.

Referring to blocks ***96*** and ***98***, if the AF episode has terminated, then the defibrillator ***20*** informs the patient and operator and instructs the operator to remove the pads ***26*** and ***28*** from the patient.

Referring to block ***120***, if the AF episode has not terminated, then the defibrillator ***20*** checks the shock counter ***58*** (**FIG. 4**) to determine if more shocks are available for the present session.

Referring to block ***122***, if there are no more shocks available in the present session, then the defibrillator ***20*** instructs the patient to call his cardiologist and wait a specified time before the next session. Next, referring to block ***98***, the defibrillator ***20*** instructs the operator to remove the pads ***26*** and ***28*** from the patient.

Referring to block ***124***, if there are more shocks available in the present session, then the defibrillator ***20*** asks the patient if he would like another shock. Referring to block ***108***, if the patient answers "yes", then the defibrillator instructs the operator to initiate the shock. Referring to block ***98***, if the patient answers "no", then the defibrillator instructs the operator to remove the pads ***26*** and ***28*** from the patient.

From the foregoing it will be appreciated that, although specific embodiments of the invention have been described herein for purposes of illustration, various modifications may be made without deviating from the spirit and scope of the invention.

WHAT IS CLAIMED:

1. An atrial defibrillator, comprising:

a portable, non-implantable housing;

a pair of defibrillator pads operable to be applied to the outside of a patient's body;

a shock generator disposed in the housing, coupled to the pads, and operable to shock the patient via the pads; and

an analyzer disposed in the housing and operable to receive a cardiac signal from the patient, to determine from the signal whether the patient is experiencing atrial fibrillation, and to enable the shock generator if the patient is experiencing atrial fibrillation.

2. The atrial defibrillator of claim 1, further comprising a control device disposed in the housing and coupled to and operable to activate the shock generator.

3. The atrial defibrillator of claim 1, further comprising a safety device disposed in the housing and operable to prevent the patient from activating the shock generator.

4. The atrial defibrillator of claim 1, further comprising a verification device disposed in the housing and operable to prevent an unauthorized person from activating the shock generator.

5. The atrial defibrillator of claim 1 wherein the analyzer is operable to receive the cardiac signal via the pads.

6. The atrial defibrillator of claim 1 wherein:

the cardiac signal comprises an electrocardiogram having R-R intervals; and

the analyzer is operable to determine whether the patient is experiencing atrial fibrillation by;

measuring the durations of the R-R intervals,

calculating the respective differences between the lengths of contiguous ones of the R-R intervals,

comparing the calculated differences to a difference threshold, and

determining that the patient is experiencing atrial fibrillation if one of the calculated differences exceeds the threshold.

7. The atrial defibrillator of claim 1 wherein:

the cardiac signal comprises an electrocardiogram having R-R intervals; and

the analyzer is operable to determine whether the patient is experiencing atrial fibrillation by;

measuring the durations of a first group of the R-R intervals,

calculating the respective differences between the durations of contiguous ones of the R-R intervals in the first group,

comparing the calculated differences to a difference threshold,

repeating the measuring, calculating, and comparing for a second group of the R-R intervals, and

determining that the patient is experiencing atrial fibrillation if one of the first-group differences and one of the second-group differences exceed the threshold.

8. The atrial defibrillator of claim 1, further comprising:

a memory coupled to the analyzer and operable to store a normal QRS signal of the patient;

wherein the cardiac signal comprises an electrocardiogram having QRS signals and R-R intervals; and

wherein the analyzer is operable to determine whether the patient is experiencing atrial fibrillation by;

measuring the durations of the R-R intervals,

calculating respective R-R differences between the lengths of contiguous ones of the R-R intervals,

comparing the calculated R-R differences to an R-R threshold,

calculating a QRS difference between one of the QRS signals of the cardiac signal and the stored QRS signal,

comparing the calculated QRS difference to a QRS threshold, and

determining that the patient is experiencing atrial fibrillation if one of the R-R differences equals or exceeds the R-R threshold and the QRS difference is less than the QRS threshold.

9. The atrial defibrillator of claim 1 wherein:

the cardiac signal comprises an electrocardiogram having R-R intervals; and

the analyzer is operable to determine whether the patient is experiencing atrial fibrillation by;

measuring the durations of the R-R intervals,

calculating respective differences between the lengths of contiguous ones of the R-R intervals,

comparing the calculated differences to a difference threshold,

determining the patient's heart rate,

determining whether the patient's heart rate is within a predetermined range of heart rates, and

determining that the patient is experiencing atrial fibrillation if one of the differences exceeds the threshold and the heart rate is within the predetermined range.

10. The atrial defibrillator of claim 1 wherein the analyzer is further operable to determine from the cardiac signal whether the atrial fibrillation terminates after the shock generator shocks the patient.

11. The atrial defibrillator of claim 1 wherein:

the cardiac signal comprises an electrocardiogram having R-R intervals; and

the analyzer is further operable to determine from the cardiac signal whether the atrial fibrillation terminates after the shock generator shocks the patient by;

measuring the lengths of the R-R intervals,

calculating respective differences between the lengths of contiguous ones of the R-R intervals,

comparing the calculated differences to a difference threshold, and

determining that the atrial fibrillation is terminated if one of the calculated differences is less than the difference threshold.

12. The atrial defibrillator of claim 1 wherein:

the cardiac signal comprises an electrocardiogram that includes an R wave having a rising edge; and

the analyzer is operable to enable the shock generator during the rising edge of the R wave and to disable the shock generator outside of the rising edge.

13. A method, comprising:

receiving a cardiac signal from a patient;

determining from the signal whether the patient is experiencing atrial fibrillation; and

shocking the patient with a portable shock generator if the patient is experiencing atrial fibrillation.

14. The method of claim 13, further comprising:

applying defibrillator pads to the patient;

wherein the receiving comprises receiving the cardiac signal via the pads; and

wherein the shocking comprises shocking the patient via the pads.

15. The method of claim 13 wherein the determining comprises:

measuring the lengths of R-R intervals in the signal;

calculating the respective differences between the lengths of contiguous ones of the R-R intervals;

comparing the calculated differences to a difference threshold; and

determining that the patient is not in atrial fibrillation if one of the calculated differences is less than the difference threshold.

16. The method of claim 13, further comprising:

storing a normal QRS signal of the patient; and

wherein the determining comprises;

measuring the lengths of R-R intervals of the cardiac signal,

calculating the respective differences between the lengths of contiguous ones of the R-R intervals,

comparing the calculated differences to an R-R threshold,

calculating a difference between a QRS signal of the cardiac signal and the stored QRS signal,

comparing the calculated QRS difference to a QRS threshold, and

determining that the patient is not in atrial fibrillation if one of the calculated differences is less than the R-R threshold or if the QRS difference is greater than or equal to the QRS threshold.

17. The method of claim 13 wherein the determining comprises:

determining the patient's heart rate; and

determining that the patient is not in atrial fibrillation if the heart rate is outside of a predetermined range.

18. The method of claim 13, further comprising determining from the cardiac signal whether the atrial fibrillation terminates after shocking the patient.

19. The method of claim 13 wherein the shocking comprises shocking the patient during a rising edge of an R wave in the cardiac signal.

20. A method, comprising:

receiving a cardiac signal from a patient;

determining from the signal whether the patient is experiencing atrial fibrillation;

identifying an operator of a shock generator;

enabling the shock generator if the operator is authorized to operate the shock generator; and

shocking the patient with the shock generator in response to a shock command from the operator if the patient is experiencing atrial fibrillation.

21. The method of claim 20, further comprising disabling the shock generator if the operator is identified as the patient.

ABSTRACT

An atrial defibrillator includes a portable, non-implantable housing, a pair of defibrillator pads, a shock generator, and an analyzer. The pads are applied to the outside of a patient's body, and the shock generator delivers a shock to the patient via the pads. The analyzer receives a cardiac signal from the patient, determines from the signal whether the patient is experiencing atrial fibrillation, and enables the shock generator if the patient is experiencing atrial fibrillation. Unlike conventional external atrial defibrillators, such an atrial defibrillator can be used by a layperson in the comfort of a patient's own home. Furthermore, such a defibrillator does not cause the surgery-related problems associated with implantable atrial defibrillators. Moreover, because the patient can choose when to receive a shock, such a defibrillator is less likely to surprise and embarrass the patient than automatic implantable defibrillators are.

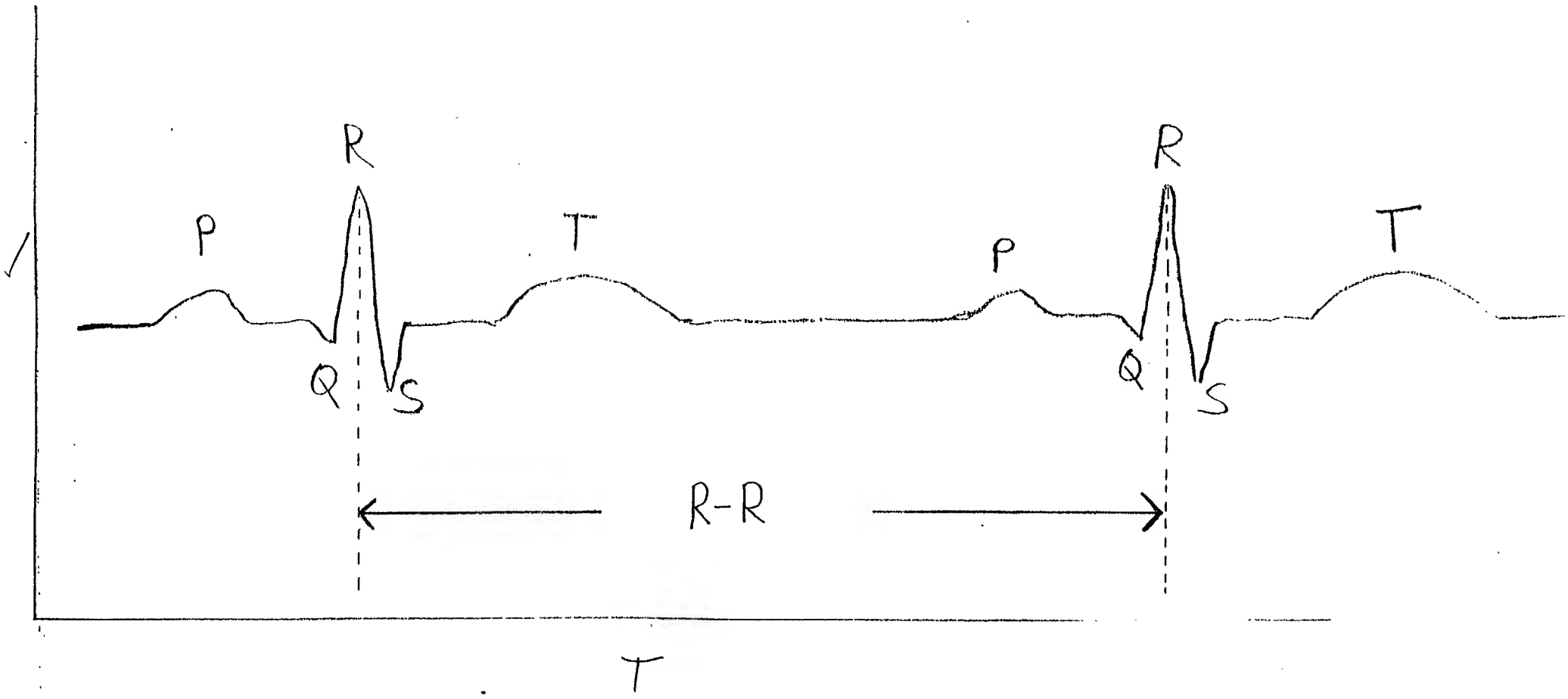

Figure 1 (Prior Art)

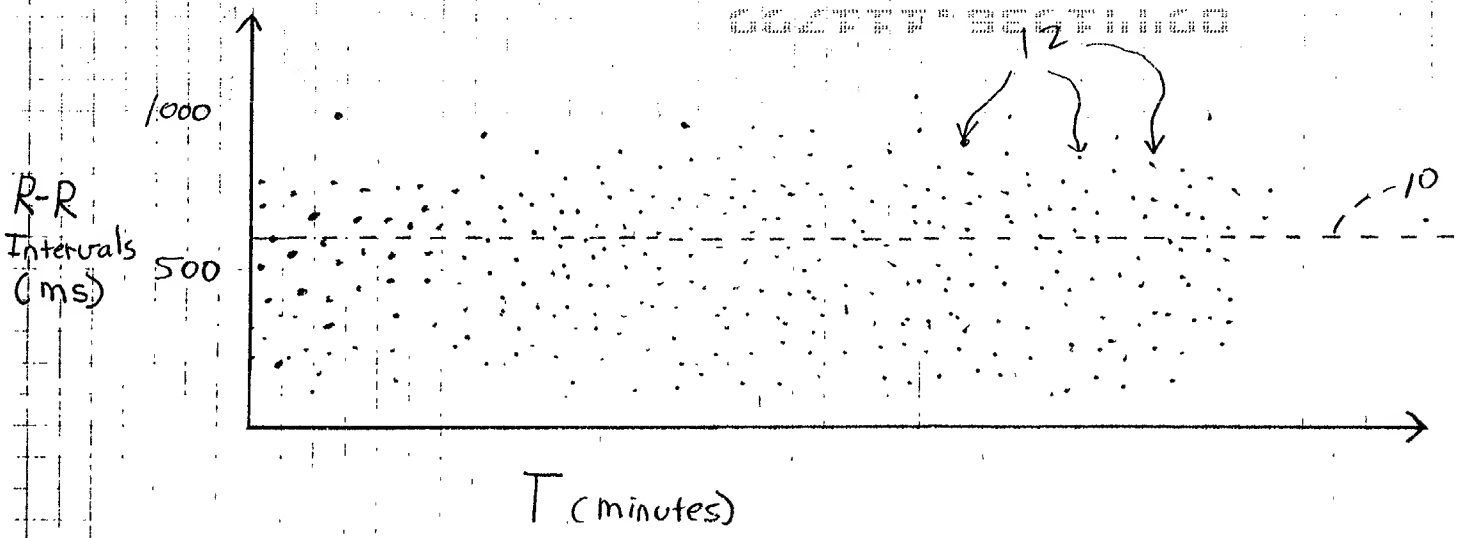

Figure 2 (Prior Art)

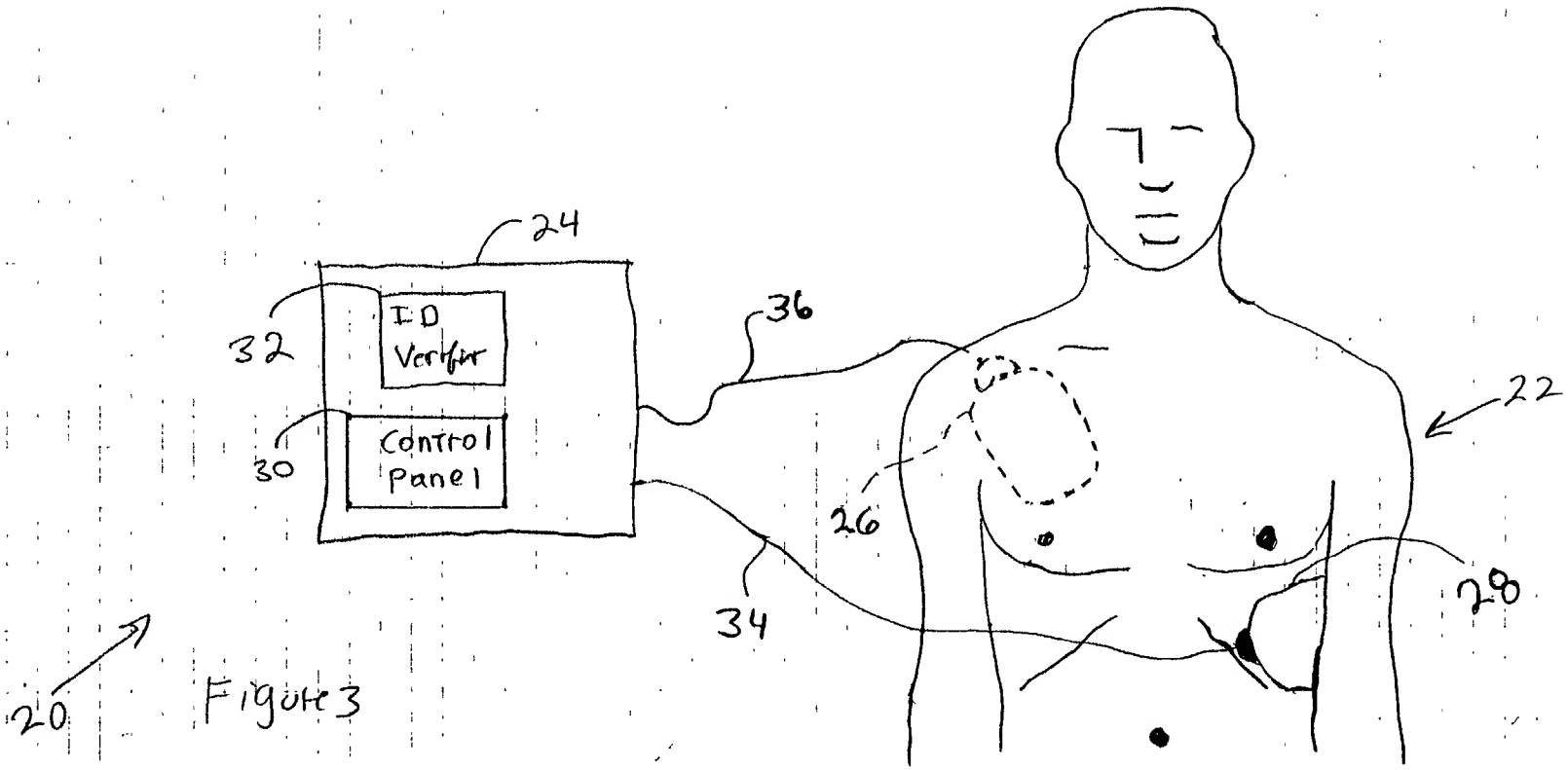

Figure 3

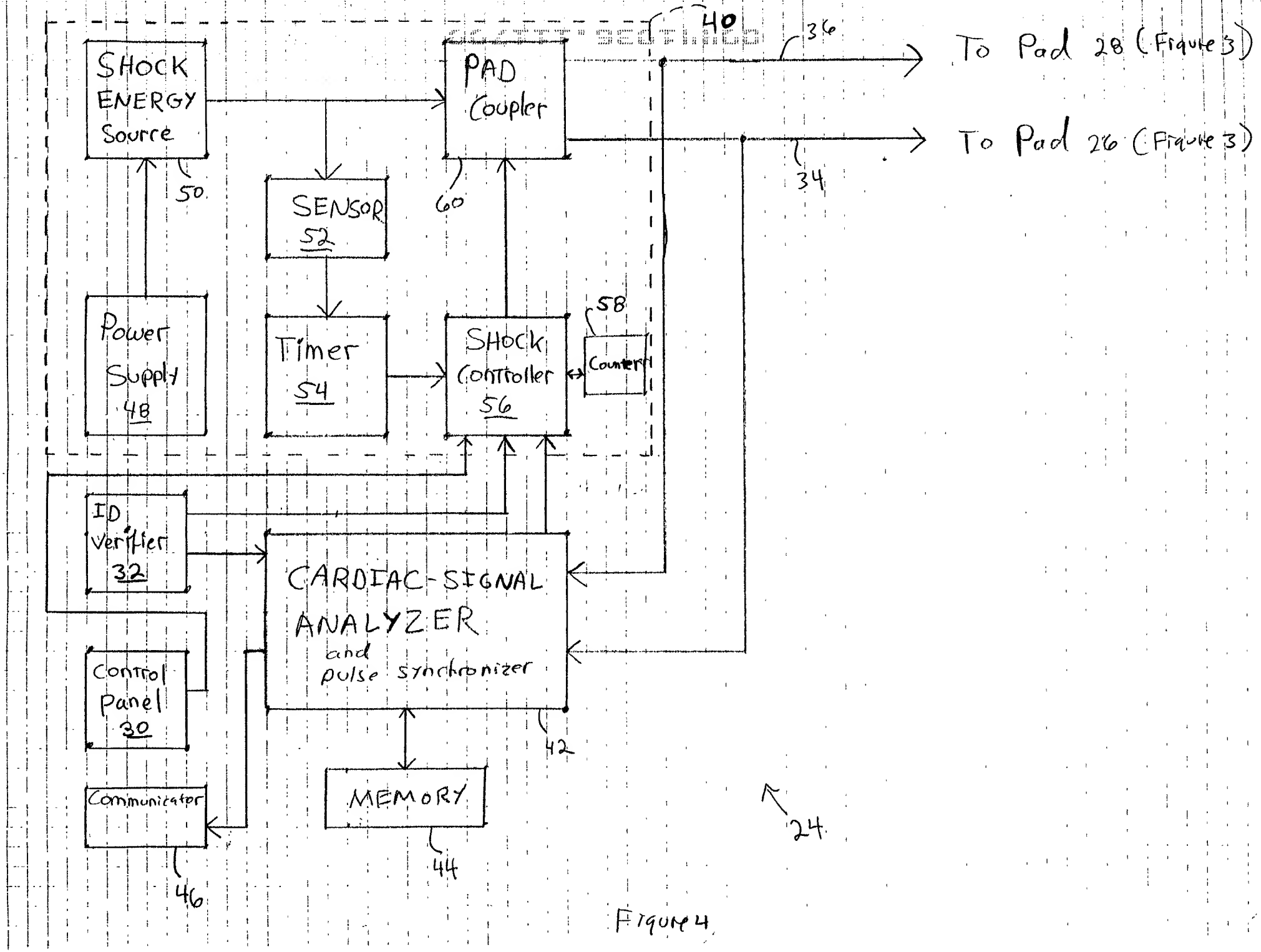
40
SHOCK ENERGY Source
50
PAD Coupler
36
To Pad 28 (Figure 3)
To Pad 26 (Figure 3)
34
60
SENSOR 52
Power Supply 48
Timer 54
SHOCK Controller 56
58
Counter
ID Verifier 32
CARDIAC-SIGNAL ANALYZER and pulse synchronizer
42
Control Panel 30
MEMORY
44
Communicator
46
24

FIGURE 4

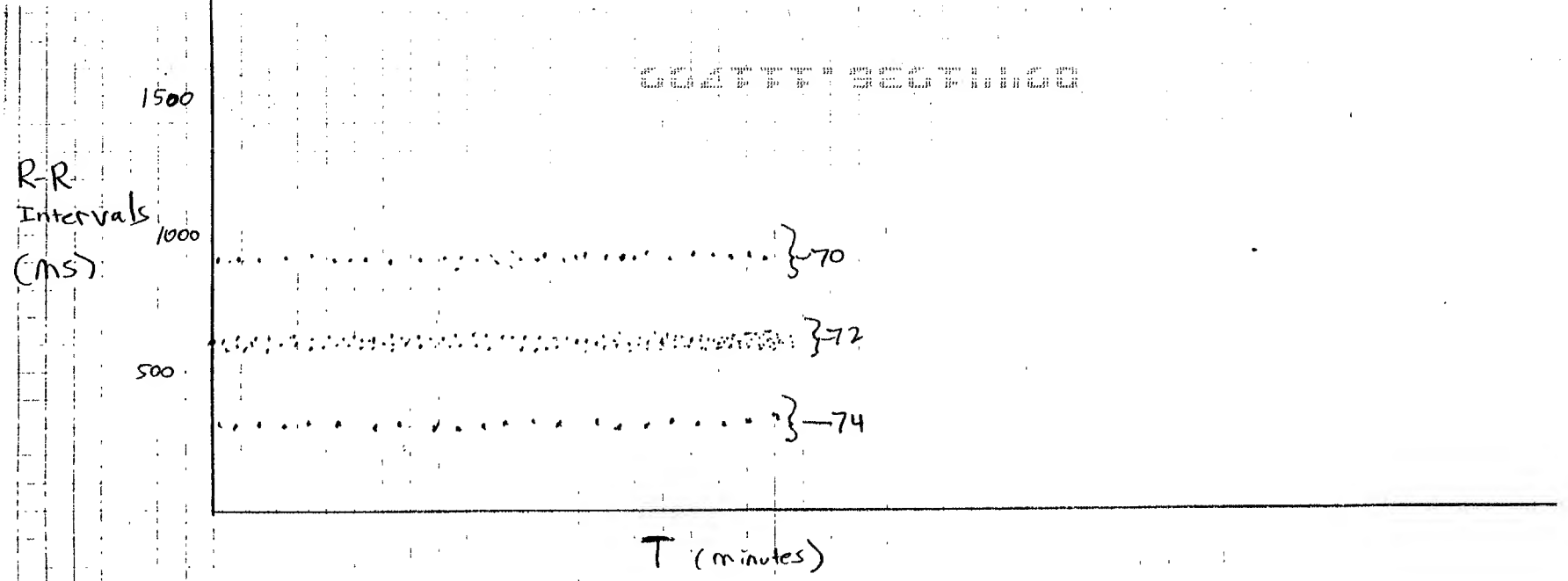

Figure 5

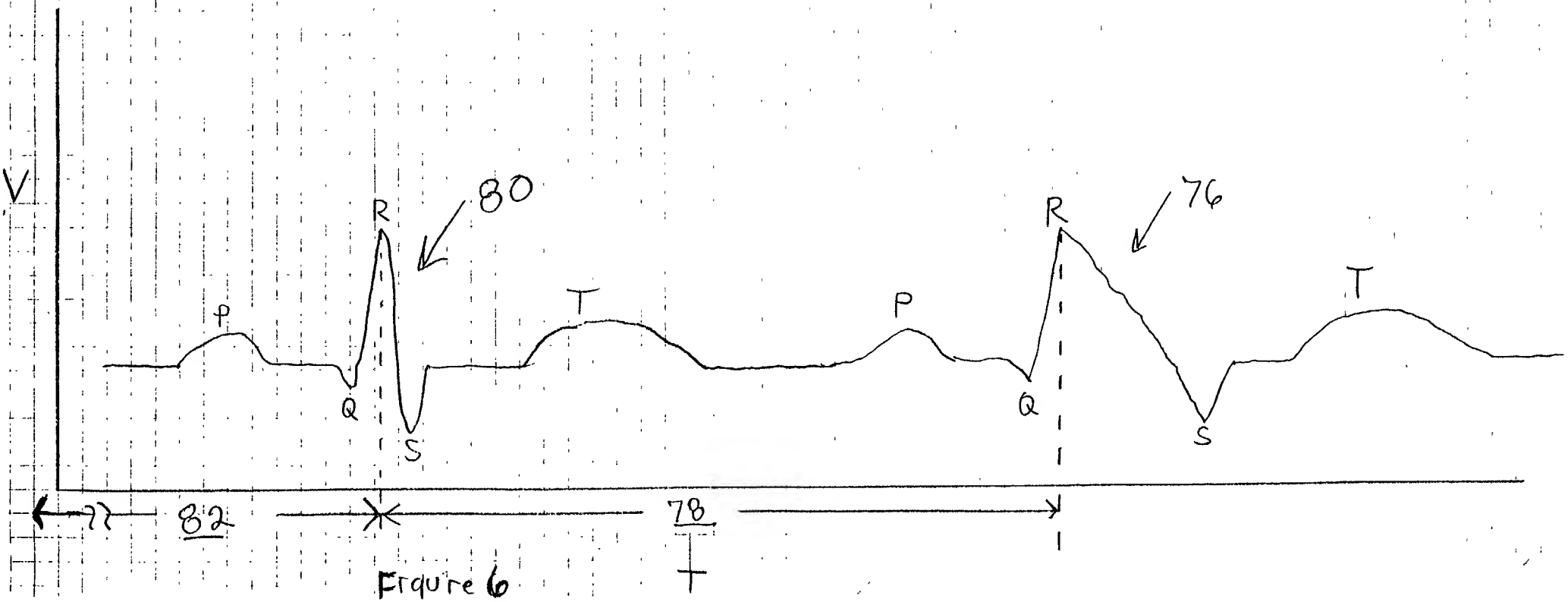

Figure 6

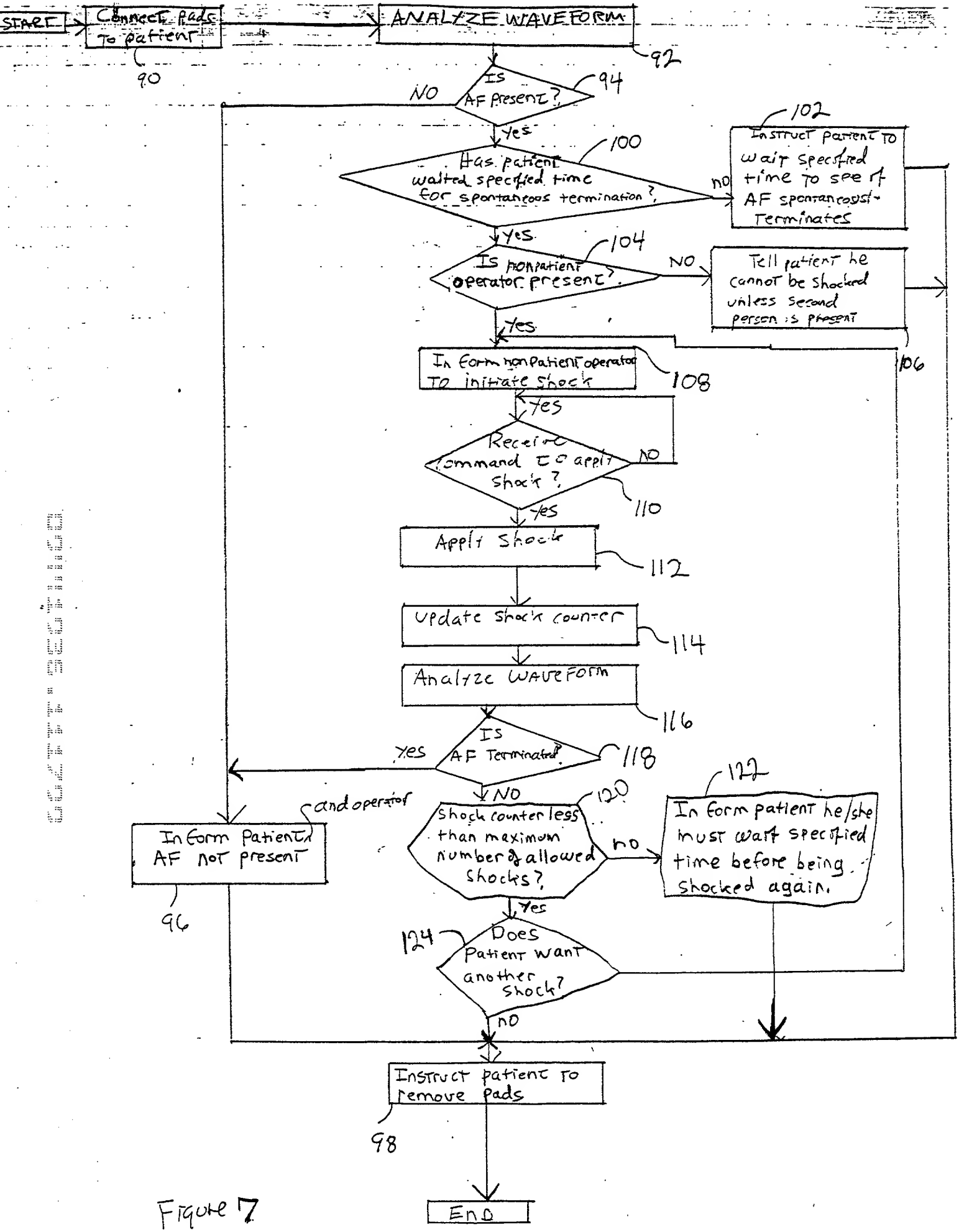
START
Connect pads to patient
90
ANALYZE WAVEFORM
92
Is AF present?
94
NO
Yes
Has patient waited specified time for spontaneous termination?
100
no
Instruct patient to wait specified time to see if AF spontaneously terminates
102
Yes
Is nonpatient operator present?
104
NO
Tell patient he cannot be shocked unless second person is present
106
Yes
In form nonpatient operator To initiate shock
108
Yes
Receive command to apply shock?
NO
110
yes
Apply Shock
112
Update shock counter
114
Analyze WAVEFORM
116
Is AF Terminated?
118
yes
NO
In form Patient AF not present
and operator
96
Shock counter less than maximum number of allowed shocks?
120
no
In form patient he/she must wait specified time before being shocked again.
122
Yes
Does Patient want another shock?
124
no
Instruct patient to remove pads
98
End

Figure 7

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

ATTORNEY DOCKET NO. 90980054-1 (1727-1)

As a below named inventor, I hereby declare that:

My residence/post office address and citizenship are as stated below next to my name;

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

EXTERNAL ATRIAL DEFIBRILLATOR AND METHOD FOR PERSONAL TERMINATION OF ATRIAL FIBRILLATION

the specification of which is attached hereto unless the following box is checked:

( ) was filed on _____ as US Application Serial No. or PCT International Application Number _____ and was amended on _____ (if applicable).

I hereby state that I have reviewed and understood the contents of the above-identified specification, including the claims, as amended by any amendment(s) referred to above. I acknowledge the duty to disclose all information which is material to patentability as defined in 37 CFR 1.56.

Foreign Application(s) and/or Claim of Foreign Priority

I hereby claim foreign priority benefits under Title 35, United States Code Section 119 of any foreign application(s) for patent or inventor(s) certificate listed below and have also identified below any foreign application for patent or inventor(s) certificate having a filing date before that of the application on which priority is claimed:

COUNTRY	APPLICATION NUMBER	DATE FILED	PRIORITY CLAIMED UNDER 35 U S.C 119
			YES ___ NO. ___
			YES ___ NO: ___

Provisional Application

I hereby claim the benefit under Title 35, United States Code Section 119(e) of any United States provisional application(s) listed below:

APPLICATION SERIAL NUMBER	FILING DATE

U. S. Priority Claim

I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code Section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Section 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

APPLICATION SERIAL NUMBER	FILING DATE	STATUS (patented/pending/abandoned)

POWER OF ATTORNEY:

As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) listed below to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

Customer No. 020067 and Customer No. 000996

Send Correspondence to:	Direct Telephone Calls To:
IP Administration Legal Department, 20BN HEWLETT-PACKARD COMPANY P.O. Box 10301 Palo Alto, California 94303-0890	Cecily Snyder (408) 553-3068

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Residence: 2518 Constance Drive West, Seattle, Washington 98199-3017

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Gust H Bardy
Inventor's Signature

Oct 28, 1999
Date

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Residence: 377 Grangeover Avenue, London, Ontario, Canada N6G 4K7

Post Office Address: Same as above

Inventor's Signature 11 5 99 Date

Full Name of # 3 joint inventor: _____ Citizenship: _____

Residence: _____

Post Office Address: _____

Inventor's Signature _____ Date

Full Name of # 4 joint inventor: _____ Citizenship: _____

Residence: _____

Post Office Address: _____

Inventor's Signature _____ Date

Full Name of # 5 joint inventor: _____ Citizenship: _____

Residence: _____

Post Office Address: _____

Inventor's Signature _____ Date

Full Name of # 6 joint inventor: _____ Citizenship: _____

Residence: _____

Post Office Address: _____

Inventor's Signature _____ Date

Full Name of # 7 joint inventor: _____ Citizenship: _____

Residence: _____

Post Office Address: _____

Inventor's Signature _____ Date

Full Name of # 8 joint inventor: _____ Citizenship: _____

Residence: _____

Post Office Address: _____

Inventor's Signature _____ Date